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U.S. DISTRICT COURT EASTERN DISTRICT OF NEW YORK

Attorney for [under seal]

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. : [UNDER SEAL],

6646

Plaintiffs,

Defendants.

COMPLAINT FOR VIOLATIONS OF FEDERAL CIVIL FALSE CLAIMS ACT

[31 U.S.C §§ 3729 et seq.]

VS.

[UNDER SEAL],

(FILED IN CAMERA AND UNDER SEAL)

ROSS, J.

REYES, M.J

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

Cons No.

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UNITED STATES OF AMERICA ex rel. CKD PROJECT, LLC, Plaintiffs,	: :	COMPLAINT FOR VIOLATIONS OF FEDERAL CIVIL FALSE CLAIMS ACT [31 U.S.C §§ 3729 et seq.]
vs.	:	JURY TRIAL DEMANDED
FRESENIUS MEDICAL CARE AG&CO KGaA, FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, NEW YORK DIALYSIS SERVICES, INC., FMS NEW YORK SERVICES LLC, BIO-MEDICAL APPLICATIONS MANAGEMENT COMPANY, INC.,	:	(FILED IN CAMERA AND UNDER SEAL)
Defendants.	:	
X		

Plaintiff-Relator CKD Project, LLC ("Relator") through its attorneys of record, on behalf of the United States of America, for its Complaint against Defendants Fresenius Medical Care AG & Co. KGaA, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, Inc., New York Dialysis Services, Inc., FMS New York Services LLC, and Bio-Medical Applications Management Company, Inc. (collectively, "Fresenius"), alleges as follows:

I. NATURE OF THE ACTION

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1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and

caused to be made by Fresenius and/or its agents, employees and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq.

- 2. As detailed below, Fresenius knowingly entered into fraudulent joint ventures with and acquisitions of physician practice groups servicing dialysis patients suffering from End Stage Renal Disease ("ESRD") in New York State and elsewhere, through which Fresenius paid physicians and others valuable and varied forms of remuneration for the purpose of inducing the referral of dialysis patients and acquiring controlling interests in dialysis clinics servicing those patients. Fresenius implemented this fraudulent scheme through a series of agreements between corporate entities controlled by Fresenius and physician practice groups owning clinics that were sources of dialysis patient referrals. The agreements provided for the transfer of valuable consideration to the physician groups in exchange for a controlling ownership interest in the dialysis clinics, the referral of the clinics' dialysis patients to the resulting Fresenius-controlled dialysis clinics, and an agreement by the physician groups not to compete with the Freseniuscontrolled dialysis clinics. Put bluntly, Fresenius paid for dialysis patient referrals, and it did so handsomely. These agreements constituted egregious violations of the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)) and generated untold numbers of false claims submitted to the Medicare and Medicaid Programs for which Fresenius wrongfully received reimbursement.
- 3. The fraudulent practices described above constituted "false and fraudulent" claims under the Federal Civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729, et seq. Such claims cheated the government and unlawfully enriched Fresenius. Therefore, Relator seeks to recover all available damages, civil penalties, and other relief for violations alleged herein.

II. PARTIES

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- 4. Plaintiff-Relator CKD Project, LLC is a New York limited liability company headquartered on Long Island and formed for the purpose of commencing this lawsuit under the False Claims Act.
- 5. Defendant Fresenius Medical Care AG & Co. KGaA ("FMC") is a German Partnership limited by shares, and headquartered in Bad Homburg, Germany. FMC's shares are listed on both the Frankfurt (stock symbols, FME, FME3) and New York (stock symbols, FMS, FMS/P) Stock Exchanges. Defendant Fresenius Medical Care Holdings, Inc., is a New York corporation wholly owned by FMC and doing business as Fresenius Medical Care North America ("FMCNA"), which is headquartered at 920 Winter Street in Waltham, Massachusetts. FMCNA operates more than 2,150 outpatient dialysis facilities throughout North America and is the leading dialysis services provider in the United States.
- 6. Defendant New York Dialysis Services, Inc. ("New York Dialysis") is a New York corporation, with a principal business address of 920 Winter Street in Waltham, Massachusetts. The Chief Executive Officer of New York Dialysis Services, Inc. is listed on the New York Department of State's website as Ronald J. Kuerbitz, who is also the Chief Executive Officer of Fresenius Medical Care North America.
- 7. Defendant FMS New York Services LLC ("FMS New York") is a Delaware corporation licensed to do business in New York. The sole member of FMS New York is defendant Bio-Medical Applications Management Company, Inc. The principal business address of FMS New York Services LLC is 920 Winter Street in Waltham, Massachusetts.

8. Defendant Bio-Medical Applications Management Company, Inc. ("Bio-Medical") is a Delaware corporation and the sole member of FMS New York, with a principal business address of 920 Winter Street in Waltham, Massachusetts.

III. JURISDICTION AND VENUE

- 9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator is the original source of the facts and information alleged in this Complaint.
- 10. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), because that section authorizes nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in this District and/or transact business in this District, and multiple acts constituting violations of 31 U.S.C. § 3729, as alleged herein, occurred in this District.
- Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because Defendants can be found in and/or transacts business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District and/or can otherwise be found and reside in this District. In addition, multiple acts constituting violations of 31 U.S.C. § 3729, as alleged herein, occurred in this District.

IV. APPLICABLE LAW

A. The False Claims Act

- 12. The FCA was originally enacted during the Civil War and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.
- 13. The FCA prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A). Additionally, it prohibits knowingly making or using a false or fraudulent record or statement "material to a false or fraudulent claim" paid or approved by the federal government, or "material to an obligation to pay" money to the government and further prohibits knowingly concealing and improperly avoiding or decreasing "an obligation to pay" money to the government. 31 U.S.C. § 3729(a)(1)(B), (G).
- 14. Pursuant to 31 U.S.C. § 3729(a)(1)(B), a false or fraudulent statement or record that is made for the purpose of causing the government to pay a claim, even if the fraudulent statement or record is not proffered directly to the government, is still actionable where there is some nexus between the statement or record and the payment of the claim. Furthermore, both affirmative misrepresentations and the omission of facts material to a governmental decision to pay can render a claim false under the FCA.
- 15. The FCA also prohibits two or more parties from conspiring to violate any of the liability provisions of the statute. 31 U.S.C. § 3729(a)(1)(C). Any person who violates, or

conspires to violate, the FCA is liable for a civil penalty of up to \$11,000 per claim for claims made on or after September 29, 1999, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a).

- 16. The FCA does not require direct contact between a Defendant and the government. By its terms, the FCA imposes liability on any person who presents or *causes* to be presented a false or fraudulent claim to the government (or false statement in support of a false or fraudulent claim). See 31 U.S.C. § 3729(a).
- To "cause" an FCA violation, it is not necessary that a Defendant's fraudulent conduct be the last in the series of events that results in financial loss to the government. As applied by the courts, the standard for "causation" under the FCA is whether the submission of a false or fraudulent claim was "reasonably foreseeable" from a Defendant's actions. Under this standard, a Defendant's fraudulent conduct can occur anywhere in the chain of events leading to financial loss by the government, and can be an indirect, as well as direct, cause of the loss. Moreover, the Defendant need not be the recipient or beneficiary of the false claim. All that is required is that the Defendant, by its fraudulent conduct, set in motion a series of events which results in a reasonably foreseeable loss to the government.
- 18. The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.
- 19. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the

complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

B. False Claims and the Anti-Kickback Statute

- 20. The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits the payment or solicitation of any form of remuneration (directly or indirectly, overly or covertly, in cash or in kind) in exchange for the referral or any item or service payable under a federal health care program, including Medicare and Medicaid. Violation of the statute is a felony punishable by up to five years imprisonment. A "false claim" is defined by statute to include any claim incorporating items or services resulting from a violation of the anti-kickback statute:
 - (g) In addition to the penalties provided for in this section [i.e., 42 U.S.C. § 1320a-7b] . . . a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [31 U.S.C. §§ 3729 et seq.]
- 21. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has long been concerned with what it has previously characterized as "a proliferation of arrangements" within the health industry "between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays." HHS-OIG, Special Fraud Alert: Joint Venture Arrangements (August 1989). HHS-OIG has stated on more than one occasion that such arrangements, often referred to as joint ventures, may violate the Anti-Kickback Statute if they are designed to induce patient referrals.
 - 22. In its August 1989 Special Fraud Alert, HHS-OIG stated:

A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. . . .

Under these suspect joint ventures, physicians may become investors in a newly formed joint venture entity. The investors refer their patients to this new entity, and are paid by the entity in the form of "profit distributions." These subject joint ventures may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures.

The questionable features of these suspect joint ventures may be reflected in three areas:

- (1) The manner in which investors are selected and retained;
- (2) The nature of the business structure of the joint venture; and
- (3) The financing and profit distributions.

(Emphasis added).

- 23. Elements identified in the 1989 Alert as characteristic of suspect joint ventures included: (1) selection of investors who are in a position to make referrals; (2) one party is already engaged in a particular line of business and the joint venture is essentially a "shell" entity created to capture that business; and (3) the amount of capital investment by the physicians may be nominal or the physicians may be permitted to "borrow" the amount of their investments from the joint venture partner, essentially eliminating the need to contribute cash to the venture. As detailed below, all these elements are present in the illegal joint venture model Fresenius is using to acquire dialysis clinics and dialysis patient revenue streams in the United States.
- 24. HHS-OIG revisited the problem of suspect joint ventures in another Special Fraud Alert issued in April 2003, which focused on contractual arrangements between parties cooperating in the provision of health services. That Alert concerned situations when the owner of one kind of health care business expands into a related line of business by contracting with an existing provider of a related item of service to provide the item or service to the owner's

existing patient population. One example cited in the Alert was a hospital establishing a subsidiary to supply durable medical equipment ("DME") and contracting with an existing DME company to run all the operations and supply all the inventory.

- 25. In that 2003 Alert, HHS-OIG identified several factors that, "taken separately or together," could signal a prohibited contractual arrangement under the Anti-Kickback Statute, including: (1) a captive referral base of existing patients is being serviced by the new business; (2) the party making the referrals is taking little or no business risk, and making little or no financial investment in the new business; (3) the parties to the venture would otherwise be competitors for the captive referrals, each having the independent capability to provide and bill for the same services; (4) the party receiving the referrals also provides a range of administrative services to the new business, such as management, billing, personnel-related services and/or health care items and supplies; (5) the overall effect of the arrangement is to permit one party to bill for the business generated by the other party and the profits of the venture are based on the value and volume of the referrals generated; and (6) provisions exist restricting the ability of one or both parties to act in competition with the venture's business operations. As detailed below, all these elements are present in the illegal joint venture model Fresenius is using to acquire dialysis clinics and dialysis patient revenue streams in the United States.
- 26. HHS-OIG has also addressed situations in which one health care provider acquires another health care provider in a manner that violates the Anti-Kickback Statute. In a 1992 letter to the Internal Revenue Service responding to an inquiry about the application of the Anti-Kickback Statute to the acquisition of physician practices, HHS-OIG commented on a situation involving the acquisition of physician practices by a hospital or other entity, which in turn acquires other hospitals or health care providers. In this scenario, the physicians would continue

to treat patients and be affiliated through an employment relationship or otherwise with the hospital or entity that acquired their practices. Moreover, as a result of the arrangement leading to the acquisition, there would be common ownership and control of the physician practices and the hospitals by a single entity.

27. Recognizing that the acquisitions of the physician practices could arise through different types of arrangements and that the resulting relationships and affiliations might vary, HHS-OIG nonetheless concluded that the fact pattern described above posed serious difficulties under the Anti-Kickback Statute:

Typically, in the case of the acquisition of a physician practice by a hospital or other entity, there is a large, up front payment to the physician, often of many hundreds of thousands of dollars or more. This sum is asserted to be payment for the purchase of the assets of the practice. There are also payments made to the physician subsequent to the sale of the practice where the physician becomes employed by the hospital or entity or otherwise enters into a contract to provide services to patients. These payments are asserted to be compensation for services rendered to patients by the physician.

We have significant concerns under the anti-kickback statute about the type of physician practice acquisitions described in your inquiry to us. Frequently, hospitals seek to purchase physician practices as a means to retain existing referrals or to attract new referrals of patients to the hospital. Such purchases implicate the anti-kickback statute because the remuneration paid for the practice can constitute illegal remuneration to induce the referral of business reimbursed by the Medicare or Medicaid programs.

We believe the same concerns raised by hospital purchases of physician practices could also arise where another entity (such as a foundation) purchases a physician practice, when such foundation also owns or operates a hospital which benefits from referrals from those physicians.

In particular, we are concerned that the remuneration paid in connection with or as a result of the acquisition of a physician's practice could serve to interfere with the physician's subsequent judgment of what is the most appropriate care for a patient. The remuneration could result in the delivery of inappropriate care to Medicare or Medicaid beneficiaries by inducing the physician to utilize the affiliated hospital rather than another hospital or less costly facility which may provide better or more appropriate care. It could also have the effect of inflating costs to the Medicare or Medicaid programs by causing physicians to overuse inappropriately the services of a particular hospital (or other affiliated provider). This higher cost could occur directly because of the higher rates of that hospital or the ordering of unnecessary serviced or indirectly as a result of lessened competition in the marketplace. Finally, these arrangements could significantly interfere with a beneficiary's freedom of choice of providers. All these considerations are the very abuses that the antikickback statute was designed to prevent. . . .

The following are specific aspects of physician practice acquisition or subsequent activities that may implicate or result in violations of the anti-kickback statute. Our comments focus primarily on two broad issue categories: (1) the total amount paid for the physician practice and the nature and type of items for which the physician receives payment; and (2) the amount and manner in which the physician is subsequently compensated for providing services to patients.

Under the anti-kickback statute, either of the above categories of payment could constitute illegal remuneration. . Thus, it is necessary to scrutinize the payments (including the surrounding facts and circumstances) to determine the purpose for which they have been made. As part of this undertaking, it is necessary to consider the amounts paid for the practice or as compensation to determine whether they reasonably reflect the fair market value of the practice or the services rendered, in order to determine whether such items in reality constitute remuneration for referrals. Moreover, to the extent that a payment exceeds the fair market value of the practice or the value of the services rendered, it can be inferred that the excess amount paid over fair market value is intended as payment for the referral of program-related business. . . .

... Merely because another buyer may be willing to pay a particular price is not sufficient to render the price paid to be fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase.

Accordingly, when attempting to assess the fair market value (as that term is used in an anti-kickback analysis) attributable to a physician's practice, it may be necessary to exclude from consideration any amounts which reflect, facilitate or otherwise relate to the continuing treatment of the former practice's patients. This would be because any such items only have value with respect to the on-going flow of business to the practice. It is doubtful whether this value may be paid by a party who could expect to benefit from referrals from that ongoing practice. Such amounts could be considered as payments for referrals. Thus, any amount paid in excess of the fair market value of the hard assets of a physician practice would be open to question. Similarly, in determining the fair market value of services rendered by employee or contract physicians, it may be necessary to exclude from consideration any amounts which reflect or relate to past or future referrals or any amounts which reflect or are affected by the expectation or guarantee of a certain volume of business (by either the physician or the hospital). Specific items that we believe would raise a question as to whether payment was being made for the value of a referral stream would include, among other things:

- -- payment for goodwill,
- -- payment for value of ongoing business unit,
- -- payment for covenants not to compete,
- -- payment for exclusive dealing agreements,
- -- payment for patient lists, or
- -- payment for patient records.

Payments for the above types of assets or items are questionable where, as is the case here, there is a continuing relationship between the buyer and the seller and the buyer relies (at least in part) on referrals from the seller.

We believe a very revealing inquiry would be to compare the financial welfare of the physicians involved before and after the acquisition. (One can expect to find projections on this subject among materials given to prospective physician participants in these arrangements.) If the economic position of these physicians is expected to significantly improve as a result of the acquisition, it is likely that a purpose of the acquisition is to offer remuneration for the referrals which these physicians can make to the buyer. Another revealing inquiry would be to compare referral patterns before and after the acquisition, specifically, whether the sellers become increasingly "loyal" to the buyer. . . .

In sum, these arrangements raise grave questions of compliance with the anti-kickback statute. We believe that many of these arrangements are merely sophisticated disguises to share the profits of business at a hospital with referring physicians, in order to induce the physicians to steer referrals to the hospital.

Letter of D. McCarty Thornton, Associate General Counsel, Inspector General Division, to T.J. Sullivan, Technical Assistant, Office of the Chief Counsel, Internal Revenue Service (December 22, 1992) (citations omitted) (emphasis added).

28. As detailed below, all of the concerns and indicia of an Anti-Kickback Statute violation, as identified by Mr. Thornton in his letter quoted above, are present in the illegal joint venture model Fresenius is using to acquire dialysis clinics and dialysis patient revenue streams in the United States. No existing "safe harbor" recognized by the Anti-Kickback Statute or its associated regulations (42 CFR § 1001.952) protects Fresenius's illegal scheme.

C. The Federal Health Care Programs

- 29. The health care programs described in the paragraphs below, and any other government-funded healthcare programs, shall be referred to as "Federal Health Care Programs."
- 30. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, et seq. ("Medicare") is a health insurance program administered by the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with end stage renal disease and/or undergoing dialysis. Pursuant to Medicare Prescription Drug Improvement and Modernization

Act of 2003, effective January 1, 2006, Medicare Part D extended prescription drug coverage to all Medicare-eligible persons who choose to participate in the Part D program.

- 31. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid") is a health insurance program administered by the United States and individual states and is funded by federal and state taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.
- 32. The federal health care program for the United States military (formerly known as the Civilian Health and Medical Program of the Uniformed Services or CHAMPUS, and now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the federal government. Among other things, this program pays for prescription drugs for its beneficiaries.
- 33. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities, including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals (38 U.S.C. § 8126).

34. The Federal Employees Health Benefits Program provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries.

D. End-Stage Renal Disease and the Reimbursement of Dialysis Services

- 35. End-Stage Renal Disease ("ESRD") is a chronic illness characterized by permanent kidney failure that can be treated either through a kidney transplant or dialysis, a medical filtering process that replaces kidney function by removing fluids and waste from the body. Most ESRD patients must undergo some form of dialysis three times a week as part of a standard regimen. According to the United States Renal Data System, as of December 31, 2011, there were more than 430,000 dialysis patients in the United States.
- 36. Medicare provides coverage for any individual with ESRD who requires dialysis treatments. In 2011, 84 percent of hemodialysis patients and 81 percent of peritoneal dialysis patients had some type of primary Medicare coverage, and total Medicare costs for dialysis totaled approximately \$25.8 billion. Other forms of insurance, including Medicaid, will pay for dialysis-related costs not covered by Medicare.
- 37. Prior to 2011, Medicare paid dialysis facilities for the treatment of ESRD using a combination of a fixed rate (called a "composite rate") and additional payment amounts for certain other services and supplies. The composite rate paid for dialysis and related routine services such as nursing, certain drugs and supplies and certain laboratory tests. The extra payments were intended to cover a second group of "separately billable" ESRD services, which included certain injectable drugs and other laboratory tests, supplies, and blood products that were either not routine or not available in 1983 when Medicare implemented the ESRD composite rate. As of January 1, 2011, this payment system changed to require that the Centers

for Medicare & Medicaid Services ("CMS") bundle Medicare reimbursement for both groups of items and services into a single payment rate.

V. FACTS UNDERLYING THE FRAUD SCHEME

- 38. As detailed below, Fresenius knowingly executed an illegal joint venture strategy in violation of both the Anti-Kickback Statute and the False Claims Act. Specifically, Fresenius devised a fraudulent business model by which cash and other valuable remuneration were funneled through Fresenius-controlled entities to the physician-owners of dialysis clinics targeted by Fresenius for acquisition in order to induce those physicians to refer their dialysis patients, and transfer their ownership interests in the dialysis clinics, to Fresenius. These transfers were accomplished through a number of interrelated agreements that left Fresenius with a controlling interest in each dialysis clinic's operations, and that prohibited the physicians from acting in competition with the Fresenius-owned clinic.
- 39. The fraudulent business model described below, involving Fresenius's purchase of patient referrals from a dialysis group practice in Hauppauge, New York, was just one part of a much larger series of transactions involving similar illegal purchases of dialysis patient revenue streams from other New York dialysis clinics at or around the same time. Furthermore, on information and belief, Fresenius employed the same fraudulent business model as a standard practice throughout the country. Indeed, Fresenius has conceded in filings with the U.S. Securities and Exchange Commission ("SEC") that its joint ventures with nephrology physician practice groups do not comply with safe harbor requirements under the Anti-Kickback Statute and result in referrals of dialysis patients to Fresenius-owned and operated dialysis centers. Thus, Fresenius, in its Annual Report filed on February 25, 2014, states:

A number of the dialysis centers and vascular access centers we operate are owned, or managed, by joint ventures in which we hold a controlling

interest and one or more hospitals, physicians or physician practice groups hold a minority interest. Physician owners, who are usually nephrologists, may also provide medical director services and physician owners may refer patients to those centers or other centers we own and operate or to other physicians who refer patients to those centers or other centers we own and operate. While we have structured our joint ventures to comply with many of the criteria for safe harbor protection under the U.S. Federal Anti-Kickback Statute, our investments in these joint venture arrangements do not satisfy all elements of such safe harbor. While we have established comprehensive compliance policies, procedures and programs to ensure ethical and compliant joint venture business operations, if one or more of our joint ventures were found to be in violation of the Anti-Kickback Statute or the Stark Law, we could be required to restructure or terminate them. We also could be required to repay to Medicare amounts received by the joint ventures pursuant to any prohibited referrals, and we could be subject to criminal and monetary penalties and exclusion from Medicare, Medicaid and other U.S. federal and state healthcare programs. Imposition of any of these penalties could have a material adverse effect on our business, financial condition and results of operations.

SEC Form 20-F at p.6 (emphasis added).

- 40. On information and belief, this standard (and illegal) Fresenius joint venture model is encapsulated by a transaction Fresenius conducted in 2010 to acquire a dialysis facility known as Apollo-Hauppauge d/b/a Suffolk Kidney Center ("Apollo-Hauppauge"), operating at 30 Central Avenue in Hauppauge, NY. The "Apollo" in Apollo-Hauppauge referred to Apollo Healthcare, L.L.C. ("Apollo Healthcare"), a New York limited liability company co-owned by Michael S. Sloma and Dr. Donald W. Landry, Chair, Department of Medicine, Physician-in-Chief and Director, Division of Nephrology, at New York Presbyterian Hospital/Columbia University. Apollo Healthcare, located in Niagara Falls, NY, operated, designed and managed free-standing dialysis facilities in New York and elsewhere.
- 41. Apollo-Hauppauge was a joint venture of Suffolk Nephrology PLLC ("Suffolk Nephrology") and 30 Central LLC ("30 Central"), with each owning 50% of the joint venture. Apollo-Hauppauge was engaged in providing chronic outpatient dialysis services and also

supporting home dialysis services. Suffolk Nephrology was comprised of five nephrologists servicing dialysis patients in the Suffolk County region through the Apollo-Hauppauge facility.

30 Central was owned, in whole or in part, by Dr. Landry, and shared a mailing address with Apollo Healthcare in Niagara Falls, NY.

- 42. In or about 2010, Fresenius executed an illegal strategy to capture the dialysis patient revenue streams of the Apollo-Hauppauge dialysis facility through a complex series of transactions designed to convey valuable consideration to Suffolk Nephrology and 30 Central in exchange for the captive dialysis patient referral base of Suffolk Nephrology and a 75% controlling interest in a newly minted version of the same facility called FMS Hauppauge LLC ("FMS Hauppauge"). FMS Hauppauge was a Fresenius shell entity organized in Delaware. The sole member of FMS Hauppauge was another Fresenius entity named New York Dialysis Services, Inc. ("New York Dialysis Services"). Fresenius initiated this series of transactions by having New York Dialysis Services assign all of its membership interests in FMS Hauppauge for no cash consideration to Apollo-Hauppauge.
- 43. In exchange for those interests, Apollo-Hauppauge "contributed" certain assets, which were referenced in a separate Contribution and Redemption Agreement ("C&R Agreement"). Indeed, the C&R Agreement expressly stated that "Suffolk [Nephrology] and 30 Central, as owners of [Apollo-Hauppauge], will receive 100% of the membership interests in [FMS Hauppauge]" as "consideration for contribution of the assets of the Business." The "Business" was defined as "providing chronic outpatient dialysis services" at Apollo-Hauppauge's facility and "supporting home dialysis programs."
 - 44. The C&R Agreement stated that Apollo-Hauppauge, Suffolk-Nephrology and 30

Central were contributing, and FMS Hauppauge was acquiring, "substantially all of the assets" of Apollo-Hauppauge used in the "Business" that could be owned by FMA Hauppauge prior to its obtaining an Article 28 license. As discussed below, those assets included the captive dialysis patient referral base and associated revenue streams of Suffolk Nephrology. A second closing involving the transfer of so-called "Article 28 Assets" was contemplated by another agreement ("Article 28 Agreement"), which provided for the payment of separate and additional consideration to Suffolk Nephrology and 30 Central within thirty days after FMS Hauppauge obtained its Article 28 license and related regulatory approvals.

45. Section 2.2 of the C&R Agreement, which specifies the assets to be contributed by Apollo-Hauppauge, states:

For purposes of this Agreement, the term "Contributed Assets" shall mean all of the Contributor's rights, title, and interest in and to all of its properties used or useable in connection with the Business, including the following assets, rights and properties, but excluding the Excluded Assets:

- (a) all Fixed assets;
- (b) all Inventory to the extent permitted by Legal Requirements;
- (c) all Proprietary Rights;
- (d) all Proprietary Software and rights in Third-Party Software that are assignable to the Company and are listed on Schedule 2.2(d);
- (e) all Contracts that are listed on Schedule 2.2(e) (collectively, the "'Assumed Contracts"), and all rights of any nature whatsoever arising out of any such Assumed Contracts;
- (f) except for Excluded Files and Medical Records, all other files, records, documents, data, plans, proposals and all other recorded knowledge of the Contributor used or generated in connection with the Business, including research and development reports and records. production reports and

- records, service and warranty records, equipment logs, operating guides and manuals, financial and accounting records, creative materials, advertising materials, promotional materials, studies, reports, correspondence and other similar documents and records, whether in written. electronic, visual or other form;
- (g) all prepaid items relating to the Business (other than any prepaid items relating to the Leased Real Property or other Excluded Assets), including all utility and security deposits, all of which are estimated in good faith by Contributor on Schedule 2.2(g), and any contract rights arising therefrom;
- (h) <u>all rights to bill for any Home Program Epogen as it is administered</u>; and
- (i) all claims and rights relating to the Contributed Assets or the Assumed Liabilities, whether choate or inchoate, known or unknown, contingent or noncontingent, including all claims and rights of Contributor against third parties relating to the Contributed Assets or the Assumed Liabilities and including claims and rights under express or implied warranties.

(Emphasis added).

46. The C&R Agreement also specified assets to be excluded from the transaction in Section 2.3, which listed, among various excluded assets: (1) all claims of Apollo-Hauppauge under Medicare or Medicaid or against any other third party payor relating to the operation of the Clinic prior to the Effective Time, defined as December 1, 2010; and (2) all patient lists, patient appointment books and other medical records used or generated in connection with Apollo-Hauppauge's provision of dialysis services. All claims against Medicare or Medicaid after the "Effective Time" thus belonged to Apollo-Hauppauge, and all of Apollo-Hauppauge's patient lists, appointment books and other medical records were included in the assets transferred to FMS Hauppauge as part of the Article 28 Agreement.

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- designed to insure that Fresenius, through FMS Hauppauge, would continue to receive the benefit of Suffolk Nephrology's patient relationships and good will. For example, Apollo-Hauppauge was required to warrant that in the period since September 30, 2010 and prior to closing it had made reasonable efforts consistent with past practices "to preserve the goodwill of the Business and its relationships with the customers, suppliers and others with whom they deal in connection with the Business . . ." (4.19). Apollo-Hauppauge also was required to warrant that it had not "incurred any material change in its overhead costs, number of patients, Accounts Receivable or accounts payable" (4.19(iv)) and that, to the knowledge of Apollo-Hauppauge, "no patient of the Business intends to terminate or materially reduce his or her relationship with the Business, in either case as a result of the consummation" of the C&R Agreement (4.20).
- 48. Section 6.10 of the C&R Agreement, moreover, contained a severe Non-Compete Clause intended to lock in the benefits of these patient relationships for Fresenius:

Covenant Not to Compete. Contributor and each Equityholder agree that, after the Closing, the Company and its Affiliates shall be entitled to the goodwill and going concern value of the Business and to protect and preserve the same to the maximum extent permitted by law. For this and other reasons and as an inducement to the Company to enter into this Agreement, except as specifically provided for herein, for a period of eight (8) years after the Closing Date (the 'Restricted Period"), neither Contributor nor any Equityholder will engage or otherwise participate in, directly or indirectly, either as principal, officer, director, agent, proprietor, shareholder, owner, partner, consultant, manager or employee, the ownership, management, operation or control of any hemodialysis facility, acute dialysis business, or home dialysis training, support or supplies service business within ten (10) miles of the Clinic (the "Restricted Area"); provided that neither Contributor nor any Equityholder shall be deemed to be in breach of this Section 6.10 solely as a result of (i) such Person's ownership of the Closing Units or other membership interests in the Company; or (ii) during the period prior to the consummation of the Article 28 Asset Contribution Agreement, such Person's continuing ownership of

the Contributor and the Contributor's ownership of the business being managed under the Master Administrative Services Agreement. Such prohibited participation within such geographic area shall also encompass those activities that are performed by the Company and its Affiliates, which include laboratory services, CAPO services and supplies, EKG, nerve conduction velocity tests, bone densitometry, dapple flow testing, self-care and acute dialysis treatment programs, the distribution and sale of dialysis equipment and supplies, and home health care service provided to ESRD patients, including intravenous therapies, respiratory and durable medical supplies and services.

(Emphasis added).

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- 49. Fresenius, having first assigned 100% of the membership interests in FMS Hauppauge to Apollo-Hauppauge for no money, but in exchange for Apollo-Hauppauge's contribution of "assets," including the patient relationships and revenue streams described above, then proceeded to pay substantial cash remuneration to Suffolk Nephrology and 30 Central by "redeeming" those same membership interests pursuant to Section 3.3 of the C&R Agreement.
- 50. Half of Suffolk Nephrology's membership interests, equivalent to a 25% ownership interest in FMS Hauppauge, were redeemed, leaving Suffolk Nephrology with a 25% residual ownership interest in the ongoing dialysis enterprise. In exchange for that 25% ownership interest, Fresenius, through FMS Hauppauge, paid the following remuneration:
 - a. \$1,200,000 plus
 - b. 25% of Prepaid Expenses plus
 - c. 25% of the Inventory Amount plus
 - d. 25% of the Epogen Amount minus
 - e. 25% of Assumed PTO minus
 - f. Certain other payments made by wire transfer to third party creditors listed in a separate schedule to the C&R Agreement.

Prepaid Expenses were defined as prepaid expenses continuing for the benefit of the company.

Inventory Amount was defined as the aggregate acquisition cost of usable inventory of disposable dialysis and medical supplies. Epogen Amount was defined as the mutually agreed upon price for Home Program Epogen that may be administered to patients after the closing and for which FMS Hauppauge may bill as administered. Assumed PTO was defined as accrued Paid Time Off assumed by FMS Hauppauge in the transaction.

- 51. All of 30 Central's membership interests, equivalent to a 50% ownership interest in FMS Hauppauge, were redeemed. In exchange for that 50% ownership interest, Fresenius, through FMS Hauppauge, paid the following remuneration:
 - a. \$2,400,000 plus
 - b. 50% of Prepaid Expenses plus
 - c. 50% of the Inventory Amount plus
 - d. 50% of the Epogen Amount minus
 - e. 50% of Assumed PTO minus
 - f. Certain other payments made by wire transfer to third party creditors listed in a separate schedule to the C&R Agreement.
- 52. Separately, under the Article 28 Agreement, Fresenius, through FMS Hauppauge, agreed to pay at closing additional remuneration to Suffolk Nephrology and 30 Central in exchange for the Article 28 assets transferred pursuant to that Agreement, *including the patient lists, appointment books and other medical records that were transferred.* Fresenius paid the following to Suffolk Nephrology (Section 3.1):
 - a. \$133,33.33, plus
 - b. An amount equal to 25% of the security deposit under Apollo-Hauppauge's real estate lease, <u>plus</u>

c. A credit to Suffolk Nephrology's Capital Account in an amount totaling the sum of (a) and (b).

Fresenius paid the following to 30 Central (Section 3.2):

- a. \$266,666.67, plus
- b. An amount equal to 50% of the security deposit under Apollo-Hauppauge's real estate lease.
- 53. After the redemptions in the C&R Agreement, Suffolk Nephrology was required to enter a Limited Liability Company Agreement ("Operating Agreement") with FMS Hauppauge and another Fresenius entity, FMS New York. As described in Section 1.3 of the Operating Agreement, the purpose of FMS Hauppauge was to "(i) operate and manage renal dialysis programs, including outpatient hemodialysis, self-care dialysis and home dialysis training and support services at 30 Central Avenue, Hauppauge, New York (the "Center" and the "Business"); (ii) acquire and own such programs and operations in a two-step transaction; and (iii) . . . conduct the Business at additional locations within the Exclusive Territory." (emphasis added.).
- 54. Pursuant to Section 2.3 of the Operating Agreement, titled "Capital Contributions," FMS Hauppauge issued additional membership interests to FMS New York aggregating to a 75% ownership interest in FMS Hauppauge i.e., the 75% interest just acquired from Suffolk Nephrology and 30 Central pursuant to the C&R Agreement in exchange for a cash payment by FMS New York of \$3.6 million. In addition, FMS New York paid 75% of Prepaid Expenses plus Inventory Amount plus the Epogen Amount minus Assumed PTO and received a credit for those amounts in its Capital Account.
 - 55. Section 2.3 of the Operating Agreement also required Suffolk Nephrology to make a

Capital Contribution in the form of: (1) a payment equal to 25% of Prepaid Expenses <u>plus</u>
Inventory Amount <u>plus</u> the Epogen Amount <u>minus</u> Assumed PTO; and (2) a cash payment of \$157,751.50. The Operating Agreement, however, provided that Suffolk Nephrology would receive a "credit" for its working capital contributions, and that the required cash contribution of \$157,751.50 would be deducted from the \$1.2 million payment made by Fresenius to Suffolk Nephrology under the C&R Agreement.

- 56. Also concurrently with consummation of the Operating Agreement, a number of other agreements were entered into with Fresenius affiliates, the effect of which was either to convey additional remuneration to Suffolk Nephrology physicians or to secure revenue streams for dialysis support services that Fresenius would render to the newly configured business operation. Those agreements included the following:
 - a. Apollo-Hauppauge entered a Master Administrative Services Agreement ("Master Agreement") with FMS Hauppauge for the provision of certain administrative services, office space, equipment and software licenses. Pursuant to the Master Agreement, Apollo-Hauppauge paid FMS Hauppauge at least \$57,665 per month for those services.
 - b. FMS New York entered a Limited Administrative Services Agreement with FMS Hauppauge under which FMS New York received at least \$19,110 per month to provide services including billing and collection, accounting, third party contracting, dissemination of policies and procedures and education and training.
 - c. Apollo-Hauppauge entered into a Medical Director Agreement with Suffolk Nephrology that paid the medical practice \$64,000 annually for medical director services, and that was to be assigned to FMS Hauppauge upon the closing of the Article 28 Agreement.
 - d. A Fresenius affiliate, Spectra Laboratories, Inc., entered a Laboratory Services Agreement with Apollo-Hauppauge to provide laboratory testing services.
 - e. A Fresenius affiliate, Fresenius USA Marketing, Inc. entered a Product Supply Agreement with Apollo-Hauppauge to provide dialysis supplies.

57. The following two pages of the Complaint contain a schematic of Fresenius's illegal joint venture scheme.

Case 1:14-cv-06646-RRM-SJB Document 1 Filed 11/12/14 Page 28 of 39 PageID #: 28 APOLLO-HAUPPAUGE ACQUISITION SYNOPSIS

New York Dialysis Services, Inc. - Fresenius entity incorporated in New York and the sole member of FMS Hauppauge, LLC, a Fresenius shell entity organized in Delaware. New York Dialysis Services assigns all of its membership interests in FMS Hauppauge to Apollo-Hauppauge d/b/a Suffolk Kidney Center. Prior to this assignment, FMS Hauppauge has no assets, but does have a bank account, a tax identification number and authorization to do business in New York.

Apollo-Hauppauge, LLC d/b/a Suffolk Kidney Center - The acquisition target, this entity is a dialysis center organized in New York as a joint venture of Suffolk Nephrology PLLC and 30 Central LLC, and operating from 30 Central Avenue, Hauppauge, New York. Apollo-Hauppauge, in a non-cash transaction requiring its "contribution" of certain "assets" that include the dialysis patient revenue streams of Suffolk Nephrology, receives an assignment from New York Dialysis Services (i.e., Fresenius) of all the membership interests in FMS Hauppauge. Apollo-Hauppauge, now an affiliate of Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, distributes half the membership interests of FMS Hauppauge to 30 Central and the other half to Suffolk Nephrology. It also signs a Medical Director Agreement with Suffolk Nephrology that pays the practice \$64,000 annually, and signs product supply, laboratory and administrative services agreements with Fresenius entities.

FMS Hauppauge, LLC - Fresenius shell entity organized in Delaware and used as the vehicle for the acquisition. Simultaneously with the distribution of membership interests to the joint venture partners, FMS Hauppauge redeems all the membership interests of 30 Central for \$2.4 million and half the membership interests of joint venture partner Suffolk Nephrology for \$1.2 million and other consideration. Concurrently, FMS Hauppauge issues additional membership interests to FMS New York Services for a payment of \$3.6 million. As a result of the transactions, FMS New York Services becomes a 75% owner of FMS Hauppauge, with Suffolk Nephrology retaining the remaining 25% ownership interest. The dialysis operations of Apollo-Hauppauge merge with FMS Hauppauge. FMS Hauppauge enters a Master Administrative Services agreement with Apollo-Hauppauge under which FMS Hauppauge is paid at least \$57,665 per month and it enters a Limited Administrative Services Agreement with FMS New York Services, which is paid at least \$19,110 per month.

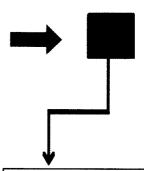
FMS New York Services LLC - Fresenius entity organized in Delaware having, as its sole member, another Fresenius entity incorporated in Delaware, Bio-Medical Applications Management Company, Inc. FMS New York Services pays \$3.6 million for a 75% ownership interest in FMS Hauppauge, which assumes the dialysis operations of the joint venture known as Apollo-Hauppauge, LLC d/b/a Suffolk Kidney Center. FMS New York Services also pays 75% of the Inventory Amounts, Epogen Amounts and Prepaid Expenses minus Assumed PTO as part of the transaction.

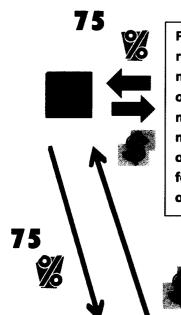
Suffolk Nephrology, PLLC -The professional nephrology practice that formed one half of the Apollo-Hauppauge joint venture operating from 30 Central Avenue, Hauppauge, New York. As part of the Fresenius acquisition and in exchange for dialysis patient revenue streams of the nephrology practice, Suffolk Nephrology received \$1.2 million, a 25% ownership interest in the ongoing dialysis enterprise and credit for capital contributions that were actually made by Fresenius rather than the practice.

30 Central LLC - Entity organized in New York that formed one half of the Apollo-Hauppauge joint venture operating from 30 Central Avenue, Hauppauge, New York. As part of the transaction, Fresenius redeemed all of 30 Central's membership interests in FMS Hauppauge for the price of \$2.4 million.

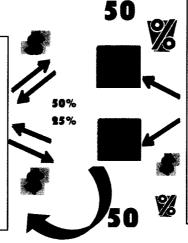


New York Dialysis Services (Fresenius entity) assigns 100% of the membership interests in FMS Hauppauge (Fresenius shell entity) to Apollo-Hauppauge d/b/a Suffolk Kidney Center. No cash is exchanged for this ownership interest, but Apollo-Hauppauge "contributes" certain "assets" to the dialysis operations of FMS Hauppauge, including the dialysis patient revenue streams of Suffolk Nephrology.





FMS Hauppauge redeems all the membership interests of 30 Central for \$2.4 million and half the membership interests of Suffolk Nephrology for \$1.2 million and other remuneration.



Apollo-Hauppauge, now an affiliate of Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, distributes 50% of the membership interests of FMS Hauppauge to 30 Central and 50% to Suffolk Nephrology. It signs a Medical Director Agreement with Suffolk Nephrology paying the practice \$64,000 annually, and signs product supply, lab and admin. services agreements with Fresenius.



Suffolk Rephrology
Dialysis Patients Go
To FMS Hauppauge

Concurrently, FMS Hauppauge issues additional membership interests to FMS New York Services (Fresenius entity) for a payment of \$3.6 million. As a result, FMS New York Services becomes a 75% owner of FMS Hauppauge and the dialysis patient revenue streams of Suffolk Nephrology. FMS Hauppauge enters a Master Administrative Services Agreement with Apollo-Hauppauge under which FMS Hauppauge receives at least \$57,665 per month.



After this series of transactions, FMS
New York Services owns a 75%
controlling interest in FMS Hauppauge,
which has acquired the dialysis patient
revenue streams of Suffolk Nephrology.
FMS New York Services enters a Limited
Administrative Services Agreement with
FMS Hauppauge under which it receives
at least \$19,110 per month. The sole
member of FMS New York Services is a
Fresenius entity incorporated in
Delaware, Bio-Medical Applications
Management Company, Inc.

- 58. It is impossible to review the details of this intricate series of transactions -- no doubt made so by Fresenius in the hope that the sheer opaqueness of the business deal would succeed in avoiding serious regulatory scrutiny -- and come away with any other conclusion but that Fresenius paid for patients in violation of the Anti-Kickback Statute. At the end of the day, Fresenius-controlled entities transferred valuable remuneration to Apollo-Hauppauge and its owners, Suffolk Nephrology and 30 Central, in exchange for dialysis patient revenue streams that Fresenius absorbed into its ever expanding dialysis operations. That remuneration took various forms, including payment of substantial cash remuneration, assumption of third-party debt and 100% deal financing on behalf of the Suffolk Nephrology medical practice. In the end, the physicians also were left with a residual 25% ownership interest in the ongoing dialysis practice, now controlled by Fresenius and backed by that company's enormous resources and marketing power. Further, a separate Medical Director agreement paid the physicians additional compensation on an annual basis going forward. Such blatant financial inducements are patently illegal. No "safe harbor" permits a dialysis leviathan like Fresenius to use the lure of economic incentives to capture the dialysis patient referral sources of nephrology practices around the country. Yet, that is precisely what happened in the case of Apollo-Hauppauge.
- 59. The acquisition model described above carries <u>ALL</u> of the hallmarks previously identified in HHS-OIG pronouncements as signifying an illegal, indeed criminal, healthcare transaction under the Anti-Kickback Statute:
 - a. Investors (<u>i.e.</u>, the Suffolk Nephrology physician practice) were selected who were in a position to make referrals;
 - b. The joint venture utilized a "shell" entity created to capture the business;
 - c. The amount of capital investment by Suffolk Nephrology was nominal or non-existent and Fresenius, the joint venture partner, effectively financed

- the physicians' investment, thereby eliminating the need for the practice group to contribute cash to the venture;
- d. The "shell" entity created to capture the business serviced a captive referral base of existing dialysis patients;
- e. Since Suffolk Nephrology, the physician practice making the referrals, made little or no financial investment, it was taking little or no business risk in the new venture;
- f. But for the transaction, the joint venture partners would otherwise be competitors for the captive referrals, each having the independent capability to provide and bill for the same services;
- g. The party receiving the referrals i.e., Fresenius also provides a range of administrative services to the new business, such as management, billing, personnel-related services and/or health care items and supplies;
- h. The overall effect of the arrangement is to permit one party to bill i.e., Fresenius -- for the business generated by the other party i.e., Suffolk Nephrology -- and the profits of the venture are based on the value and volume of the referrals generated;
- i. remuneration was paid for a non-compete provision barring one party for a period of 8 years from participating in the ownership, management, operation or control of any other dialysis-related business within a 10 mile radius;
- j. The payments made by Fresenius were intended to compensate Apollo-Hauppauge and its owners for goodwill, the value of ongoing business, exclusive dealing agreements, patient lists and patient records, in the context of a continuing business relationship in which Fresenius relied on patient referrals from Suffolk Nephrology going forward; and
- k. The economic position of Apollo-Hauppauge's owners, including the physicians of Suffolk Nephrology, improved significantly as a result of the transaction.
- 60. As a result of Fresenius's unlawful conduct in inducing referrals of dialysisrelated items and services in violation of the Anti-Kickback Statute, millions of dollars in
 dialysis-related claims were submitted by FMS Hauppauge and paid by Federal Health Care
 Programs, including Medicare, during the almost four years that have passed since the

acquisition of Apollo-Hauppauge closed. Specifically, for the one year period ending December 31, 2013, Medicare paid more than \$4 million for dialysis-related services performed at FMS Hauppauge. Approximately 65% of that amount was paid by original Medicare and approximately 25% was paid by Medicare Advantage. Over four years, it is estimated that Medicare and Medicare Advantage paid at least \$16 million for dialysis-related services at FMS Hauppauge. That is for just one facility. On information and belief, many other dialysis facilities have been the subject of the same or substantially similar illegal scheme.

- 61. Given the intricate, standardized wording and interlocking nature of the underlying transaction documents utilized in the Apollo-Hauppauge acquisition described above, and in light of Fresenius's own admissions in SEC filings that its joint venture model does not fully comply with any recognized "safe harbor" under the Anti-Kickback Statute, Relator believes that the Apollo-Hauppauge acquisition reflected a standard business practice at Fresenius, and is merely illustrative of numerous other acquisitions of dialysis facilities by Fresenius in New York and elsewhere utilizing the same or substantially similar unlawful business model.
- 62. Within New York State alone, Relator believes that, in or about the same period as the Apollo-Hauppauge transaction, Fresenius acquired at least four other dialysis facilities that were ether owned or co-owned by Apollo Healthcare and that were likewise absorbed by corporate entities maintained by Fresenius for that express purpose. On information and belief, these other facilities included FMS Niagara, LLC (located in Niagara Falls, NY), FMS Watertown, LLC (located in Watertown, NY), FMS Buffalo Artificial Kidney Center (located in Buffalo, NY) and FMS Kenmore Artificial Kidney Center (located in Tonawanda, NY). Those facilities, like FMS Hauppauge, are now owned and controlled by Fresenius, operating from its corporate headquarters at 920 Winter Street, Waltham, Massachusetts, and the dialysis patient

referrals associated with those facilities have been bought and paid for. After the Apollo Healthcare facilities were acquired, Michael Sloma, former co-owner of Apollo Healthcare, joined Fresenius, where he is Group Vice President, Strategic Development in the Buffalo/Niagara area of upstate New York.

- 63. Some of the other dialysis facilities located in New York State carrying the "FMS" moniker which are owned or controlled by Fresenius through New York Dialysis Services, Inc. i.e., the very same Waltham, Massachusetts-based entity used by Fresenius to initiate the chain of transactions described above that culminated in the acquisition of Apollo-Hauppauge include FMS-Duchess Dialysis Center (Poughkeepsie), FMS-Nephro Care, FMS-Atlantic Hemodialysis Center at Cobble Hill and FMS-Brooklyn Kidney Center (all in Brooklyn), FMS-Southern Manhattan Dialysis Center (multiple sites in upstate NY and in Manhattan) and FMS Central Suffolk Artificial Kidney Center (Port Jefferson).
- 64. In addition, a search of the Delaware corporate database reveals numerous other shell entities organized by Fresenius in Delaware which, on information and belief, operate as dialysis facilities elsewhere in the country and share the same Waltham, Massachusetts corporate address as Fresenius. Many carry the name "FMS" as with FMS Hauppauge, while others carry the name "Fresenius Medical Care." Examples of these other entities include FMS Abramson LLC (located in Pennsylvania), Fresenius Medical Care Balboa LLC (located in California) FMS Midwest Dialysis Centers LLC (located in Kansas), FMS Endeavour Dialysis Center LLC (located in Alabama), Fresenius Medical Care Batavia (located in Illinois), FMS Lansing LLC (located in Michigan), FMS Cabell Huntington Dialysis Centers LLC (located in Ohio and West Virginia), Fresenius Medical Care Camden County LLC (located in in New Jersey) and FMS Nephrology Partners North Central Indiana Dialysis Centers LLC (located in Indiana), to name

referrals associated with those facilities have been bought and paid for. After the Apollo Healthcare facilities were acquired, Michael Sloma, former co-owner of Apollo Healthcare, joined Fresenius, where he is Group Vice President, Strategic Development in the Buffalo/Niagara area of upstate New York.

- 63. Some of the other dialysis facilities located in New York State carrying the "FMS" moniker which are owned or controlled by Fresenius through New York Dialysis Services, Inc. i.e., the very same Waltham, Massachusetts-based entity used by Fresenius to initiate the chain of transactions described above that culminated in the acquisition of Apollo-Hauppauge include FMS-Duchess Dialysis Center (Poughkeepsie), FMS-Nephro Care, FMS-Atlantic Hemodialysis Center at Cobble Hill and FMS-Brooklyn Kidney Center (all in Brooklyn), FMS-Southern Manhattan Dialysis Center (multiple sites in upstate NY and in Manhattan) and FMS Central Suffolk Artificial Kidney Center (Port Jefferson).
- 64. In addition, a search of the Delaware corporate database reveals numerous other shell entities organized by Fresenius in Delaware which, on information and belief, operate as dialysis facilities elsewhere in the country and share the same Waltham, Massachusetts corporate address as Fresenius. Many carry the name "FMS" as with FMS Hauppauge, while others carry the name "Fresenius Medical Care." Examples of these other entities include FMS Abramson LLC (located in Pennsylvania), Fresenius Medical Care Balboa LLC (located in California) FMS Midwest Dialysis Centers LLC (located in Kansas), FMS Endeavour Dialysis Center LLC (located in Alabama), Fresenius Medical Care Batavia (located in Illinois), FMS Lansing LLC (located in Michigan), FMS Cabell Huntington Dialysis Centers LLC (located in Ohio and West Virginia), Fresenius Medical Care Camden County LLC (located in Indiana), to name

just a few. There are numerous other entries in the Delaware corporate database. On information and belief, these and numerous other dialysis facilities around the country were acquired by Fresenius through a substantially similar acquisition model to that utilized by Fresenius to acquire Apollo-Hauppauge and the dialysis patient relationships and revenue streams of Suffolk Nephrology, as described above.

65. Fresenius executed the fraudulent business strategy described above for the purpose of inducing dialysis patient referrals to Fresenius-owned and controlled entities and billing the Federal Health Care Programs for dialysis-related services. Fresenius's unlawful conduct, perpetrated throughout New York State and elsewhere, has caused millions of dollars in losses to the United States, which has paid tens of thousands of false claims for referrals of items and services that Fresenius generated in violation of the Anti-Kickback Statute.

VI. <u>CAUSES OF ACTION</u>

COUNT ONE (Federal False Claims Act) 31 U.S.C. § 3729(a)(1)(A)

- 66. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 65 above as though fully set forth herein.
- 67. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, et seq., as amended.
- 68. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States government for payment or approval. 31 U.S.C. § 3729(a)(1)(A).
 - 69. The United States, unaware of the falsity of the claims made or caused to be made

by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

- 70. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 71. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO (Federal False Claims Act) 31 U.S.C. § 3729(a)(1)(B)

- 72. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 65 above as though fully set forth herein.
- 73. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted facts, that were material to false or fraudulent claims, within the meaning of 31 U.S.C. § 3729(a)(1)(B).
- 74. The United States, unaware of the falsity of the records, statements and material omissions made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.
- 75. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 76. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT THREE (Federal False Claims Act) 31 U.S.C. § 3729(a)(1)(C)

- 77. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 65 above as though fully set forth herein.
- 78. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, et seq., as amended.
- 79. By virtue of the acts described above, Defendants conspired with others known and unknown to defraud the United States by inducing the United States to pay or approve false and fraudulent claims, and to avoid and conceal an obligation to pay money and property, within the meaning of 31 U.S.C. § 3729(a)(1)(C). Defendants, moreover, took substantial steps in furtherance of the conspiracy, *inter alia*, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.
- 80. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 81. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every violation of 31 U.S.C. § 3729(a)(1)(C) as described herein.

COUNT FOUR (Federal False Claims Act) 31 U.S.C. § 3729(a)(1)(G)

- 82. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 65 above as though fully set forth herein.
 - 83. By virtue of the acts described above, Defendants knowingly made, used, or caused

to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, within the meaning of 31 U.S.C. § 3729(a)(1)(G).

- 84. The United States, unaware of the falsity of the records and statements and of the Defendants' concealment and unlawful conduct, was denied an opportunity to claim and demand return of the money and property to which it was legally entitled.
- 85. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 86. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relator, acting on behalf and in the name of the United States of America, demands and prays that judgment be entered against Defendants under the Federal False Claims Act as follows:

- (1) That Defendants cease and desist from violating 31 U.S.C. §§ 3729 et seq., as set forth above;
- (2) That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729; and

- (6) That Relator be awarded all costs of this action, including attorneys' fees and expenses; and
 - (7) That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: November <u>12</u>, 2014

By:

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